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| 09/762,522 | 02/05/2001 | Maria Altamura | 205 010 | 4796 |

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EXAMINER

COLEMAN, BRENDA LIBBY

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| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/762,522

Applicant(s)

ALTAMURA ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 28 October 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): See attached action.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: 23,24,26,27,30,31 and 35.Claim(s) rejected: 21,22,25,28,29 and 32-34.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Art Unit: 1624

ADVISORY ACTION

Claims 21-35 are pending in the application.

The period for reply continues to run SIX MONTHS from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 or a request for a continued examination (RCE) in compliance with 37 CFR 1.114 must be timely filed to avoid abandonment of this application.

The amendment filed March 2, 2004 under 37 CFR 1.116 in reply to the final rejection has been entered, but is not deemed to place the application in condition for allowance. For purposes of appeal, the status of the claims is as follows:

Allowed claim(s): none

Rejected claim(s): 21, 22, 25, 28, 29 and 32-34

Claim(s) objected to: 22, 23, 26, 27, 30, 31 and 35

This action is in response to applicant's amendment dated March 2, 2004. Claims 21-23 and 27-29 have been amended and claims 34 and 35 are newly added.

Response to Arguments

Applicant's arguments filed March 2, 2004 have been fully considered with the following effect:

Art Unit: 1624

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 1d), maintained in the office action dated April 29, 2003, which is hereby withdrawn. However, with regards to the 35 U.S.C. § 112, first paragraph rejections labeled g) and h) maintained in the office action dated April 29, 2003, the applicant's amendments and remarks have been fully considered but they are not persuasive.

g) The applicants failed to acknowledge the rejection to the definition of R_9 in the amendment to the specification where R_9 is 4-tetraiodothiopyranyl in the amendment to the specification filed February 12, 2003. The definition of R_9 on page 5, line 15 has been amended such that the moiety 4-tetraiodothiopyranyl was amended to 4-tetraiodothiopyranyl. However, at no time can the thiopyranyl be substituted four times with an iodo moiety. It is believed that the applicants intended 4-tetrahydrothiopyranyl.

h) The applicants failed to acknowledge the rejection to the definition of R_9 in the amendment to the specification where R_9 is 1-oxotetraiodothiopyran-4-yl in the amendment to the specification filed February 12, 2003. The definition of R_9 on page 5, line 16 has been amended such that the moiety 1-oxotetraiodothiopyran-4-yl was amended to 1-oxotetraiodothiopyran-4-yl. However, at no time can the thiopyranyl be substituted four times with an iodo moiety. It is believed that the applicants intended 1-oxotetrahydrothiopyran-4-yl.

Art Unit: 1624

Applicant is required to cancel the new matter in the reply to this Office Action.

2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 2, subparagraphs g), o), y), af), ag), an) and as), maintained in the office action mailed February 12, 2003, which are hereby **withdrawn**.

3. The applicant's amendments are sufficient to overcome the objection to the disclosure labeled paragraph 3 in the office action mailed February 12, 2003, which is hereby **withdrawn**.

4. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 7 of the office action mailed February 12, 2003, which is hereby **withdrawn**.

5. The applicant's amendments and arguments are sufficient to overcome the objection to the specification labeled paragraph 8a) of the office action mailed February 12, 2003, which is hereby **withdrawn**. However, with regards to the objection to the specification labeled paragraph 8b), the applicants failed to acknowledge the objection to the definition of R₉ in the amendment to the specification where R₉ is N-methanesulfonyl-4-piperidinyl. It is believed that the applicants intended N-methanesulfonyl-4-piperidinyl

6. The applicant's amendments and arguments are sufficient to overcome the newly added 35 U.S.C. § 112, second paragraph rejections labeled

Art Unit: 1624

paragraph 9a), of the office action mailed February 12, 2003, which is hereby **withdrawn**.

In view of the amendment dated March 2, 2004, the following new grounds of rejection and/or remaining issues apply:

Specification

7. The disclosure is objected to because of the following informalities:

a) The amendment to page 1, lines 18-19 of the amendment filed March 2, 2004 is missing a comma between the moieties -NRCO- and -CH₂-NR-, i.e. X₁, X₂, X₃, X₄, same or different, are a group chosen among: -CONR-, -NRCO- -CH₂-NR-, -NR-CH₂- where R is H, C₁₋₃ alkyl, or benzyl;

b) The amendment to page 1, lines 22-27 of the amendment filed March 2, 2004 has an "and" between the moieties C₁₋₃ alkyloxy and C₂₋₄ amino-alkyloxy which should not be there, but a comma should. The "and" should be after the CN moiety to indicate the end of the Markush grouping. Additionally, thiophene is spelled wrong. The paragraph should be as shown below (emphasis added):

-(CH₂)_rAr where r is 0, 1 or 2 and Ar is an aromatic group chosen among benzene, naphthalene, thiophene, benzothiophene, pyridine, quinoline, indole, furan, benzofuran, thiazole, benzothiazole, imidazole, benzoimidazole, possibly substituted with up to 2 substituents chosen among C₁₋₃ alkyl, C₁₋₃ haloalkyl, C₁₋₃ alkyloxy, C₂₋₄ amino-alkyloxy,

Art Unit: 1624

halogens, OH, NH₂, CN, **and** NR₆R₇, where R₆ and R₇, are the same or different, and are H or C₁₋₃ alkyl;

c) The amendment to page 1, lines 22-27 of the amendment filed February 12, 2003 has an "and" between the moieties C₁₋₃ alkyloxy and C₂₋₄ amino-alkyloxy which should not be there, but a comma should. The "and" should be after the CN moiety to indicate the end of the Markush grouping. Additionally, benzene is spelled wrong. The paragraph should be as shown below (emphasis added):

-(CH₂)_rAr₁ where r is 0, 1 or 2 and Ar₁ is an aromatic group chosen among: ben[e]zene, naphthalene, thiophene, benzothiophene, pyridine, quinoline, indole, furan, benzofuran, thiazole, benzothiazole, imidazole, benzoimidazole, possibly substituted with up to 2 groups chosen among: C₁₋₃ alkyl, C₁₋₃ haloalkyl, C₁₋₃ alkyloxy, C₂₋₄ amino-alkyloxy, halogens, OH, NH₂, CN, **and** NR₆R₇, where R₆ and R₇, are the same or different, and are H or C₁₋₃ alkyl;

d) The applicant's attention is also directed to the following pages, which include additional typographical errors, for example:

- 1) Page 6, line 13, should be CF₃ not CF3;
- 2) Page 6, line 15, is missing an open parenthesis on the (R)-NH- which should be [(R)-NH-;
- 3) Page 6, line 17, is missing an open parenthesis on the (R)-NH- which should be [(R)-NH-;

Art Unit: 1624

- 4) Page 7, line 1, R₁, R₂, R₃ should be R₁, R₂, R₃;
- 5) Page 7, line 3, R₉ should be R₉;
- 6) Page 7, line 4, (CH₂)_g-R₁₀ should be (CH₂)_g-R₁₀;
- 7) Page 7, line 5, should have an "or" between furan, and CN;
- 8) Page 7, line 23, R₁, R₂, R₃ should be R₁, R₂, R₃;
- 9) Page 7, line 25, R₄ should be R₄;
- 10) Page 7, line 26, R₁₂ should be R₁₂;
- 11) Page 9, line 7, R₁, R₂, R₃ should be R₁, R₂, R₃;
- 12) Page 7, line 25, R₄ should be R₄;
- 13) see also pages 10, 11, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32 and 33

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed March 2, 2004 inserting new independent claim 34 where the definition of R₁₂ is 4-aminosulfonyl-piperazine and 4-hydroxy-cyclohexan-1-yl-

Art Unit: 1624

amion is not described in the specification with respect to the genus of formula

(I). These moieties are not positively described in the specification with respect to formula (I).

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 21, 22, 25, 28, 29, 32, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a) Claim 21 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the definition of the substituents on the Ar₁ moieties where the carbon count for the amino-alkyloxy is missing, i.e. C₂₋₄ amino-alkyloxy. See page 7, line 2 of the amendment filed March 2, 2004.

b) Claim 25 is vague and indefinite in that it is not known what is meant by the moiety CF₃ in the species labeled xii) on page 10 of the amendment filed March 2, 2004. It is believed that the applicants intended CF₃.

c) Claim 28 is vague and indefinite in that the claim ends with a comma and then a period, i.e. ,.

Art Unit: 1624

- d) Claim 29 is vague and indefinite in that it does not end with a period.
- e) Claim 34 is vague and indefinite in that it is not known what is meant by the definition of the substituents on the Ar₁ moieties where the carbon count for the amino-alkyloxy is missing, i.e. C₂₋₄ amino-alkyloxy.
- See page 14, line 7 of the amendment filed March 2, 2004.

Claim Objections

10. Claims 23, 24, 26, 27, 30, 31 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
March 12, 2004